

DETAILED ACTION

Remarks

The previous office action that recited a restriction requirement is hereby vacated in view of the newly presented restriction requirement below.

Election/Restrictions

Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, drawn to a composition comprising a bioactive material and a vehicle with a first and second compound.

Group II, claims 10-14, drawn to a method of coating a medical device with a composition comprising a bioactive material and a vehicle with a first and second compound.

Group III, claims 15-20, drawn to a medical device comprising a coating composition comprising a bioactive material and a vehicle with a first and second compound.

Group IV, claims 22, drawn to a vehicle with a first and second compound.

The inventions listed as Groups I, II, III, and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: their common technical feature is not novel. The common technical feature of each group is a composition comprised of a bioactive, a polymer of a vinyl acetate and optionally a vinyl acetal and a vinyl alcohol, as well

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as a polymer of vinyl pyrrolidone and optionally vinyl acetate. Ding (U.S. Patent No. 7,294,329) teach a coating composition for medical devices with a bioactive along with a ternary copolymer of a vinyl acetate, a vinyl acetal and a vinyl alcohol (see claims 1-2 and 10 and column 2 lines 43-45, column 4 lines 36-38 – compound in claims of reference where $n=0$). Further, Ding also teaches the incorporation of a second polymer into the composition (see claim 10). Eder et al. (U.S. PGPub No. 2002/0087184) teach that poly(vinyl pyrrolidone) was a known polymer used in coatings for medical devices (see paragraph 36 line 6). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use poly(vinyl pyrrolidone) as the second polymer in the coating composition of Ding, thereby making obvious the common technical feature of the instant invention. Thus since, the technical feature of the invention was known in the art, this technical feature cannot be deemed as special.

If group I, II, or III is elected, then a species election is also required.

Election of Species

Claims 1-9 (group I), 10-14 (group II), and 15-20 (group III) in this application are directed to more than one species of the generic invention of Group I. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for more than one species to be examined, the appropriate additional examination fees must be paid.

Should Group I be elected then its species are as follows:

Species A: Claims 1-4 and 8-9, drawn to a coating composition with a bioactive where the second compound (formula 2) is poly(vinyl pyrrolidone-co-vinyl acetate) and the first compound is formula 1 defined such that a specific A, B,

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and C are identified.

Species B: Claims 1-2, 5-7, and 8-9 drawn to a coating composition with a bioactive where the first compound (formula 1) is poly(vinyl butyral-co-vinylalcohol-vinylacetate) and the second compound is formula 2 defined such that a specific D and E are identified.

The species listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: their common technical feature is not novel. The common technical feature of each group is a composition comprised of a bioactive, a polymer of a vinyl acetate and optionally a vinyl acetal and a vinyl alcohol, as well as a polymer of vinyl pyrrolidone and optionally vinyl acetate. The presence of this technical feature in the prior art is described above and also applies here.

Should Group II be elected then its species are as follows:

Species A: a method wherein the coating applied is a coating composition with a bioactive where the second compound (formula 2) is poly(vinyl pyrrolidone-co-vinyl acetate) and the first compound is formula 1 defined such that a specific A, B, and C are identified.

Species B: a method wherein the coating applied is a composition with a bioactive where the first compound (formula 1) is poly(vinyl butyral-co-vinylalcohol-vinylacetate) and the second compound is formula 2 defined such that a specific D and E are identified.

The species listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features

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for the following reasons: their common technical feature is not novel. The common technical feature of each group is a composition comprised of a bioactive, a polymer of a vinyl acetate and optionally a vinyl acetal and a vinyl alcohol, as well as a polymer of vinyl pyrrolidone and optionally vinyl acetate. The presence of this technical feature in the prior art is described above and also applies here.

Should Group III be elected then its species are as follows:

Species A: a medical device coated with a composition with a bioactive where the second compound (formula 2) is poly(vinyl pyrrolidone-co-vinyl acetate) and the first compound is formula 1 defined such that a specific A, B, and C are identified.

Species B: a medical device coated with a composition with a bioactive where the first compound (formula 1) is poly(vinyl butyral-co-vinylalcohol-vinylacetate) and the second compound is formula 2 defined such that a specific D and E are identified.

The species listed do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: their common technical feature is not novel. The common technical feature of each group is device coated with a composition comprised of a bioactive, a polymer of a vinyl acetate and optionally a vinyl acetal and a vinyl alcohol, as well as a polymer of vinyl pyrrolidone and optionally vinyl acetate. The presence of coating composition in the prior art is described above and also applies here. Further, Ding also teaches a medical device coated with their taught composition (see example 5). Thus it would have been obvious at the time of the invention to coat a medical device with the coating composition of Ding in view of Eder et al.

Applicant is required, in reply to this action, to elect a single invention and species A or B (if applicable) to which the claims shall be restricted if no generic claim is finally held to be allowable. If a species election is required for the elected group, then applicant must define the specified variable groups. The reply must also *identify the claims readable on the election, including any claims subsequently added*. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

The election of an invention or species may be made with or without traverse (37 CFR 1.143). To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-83738373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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